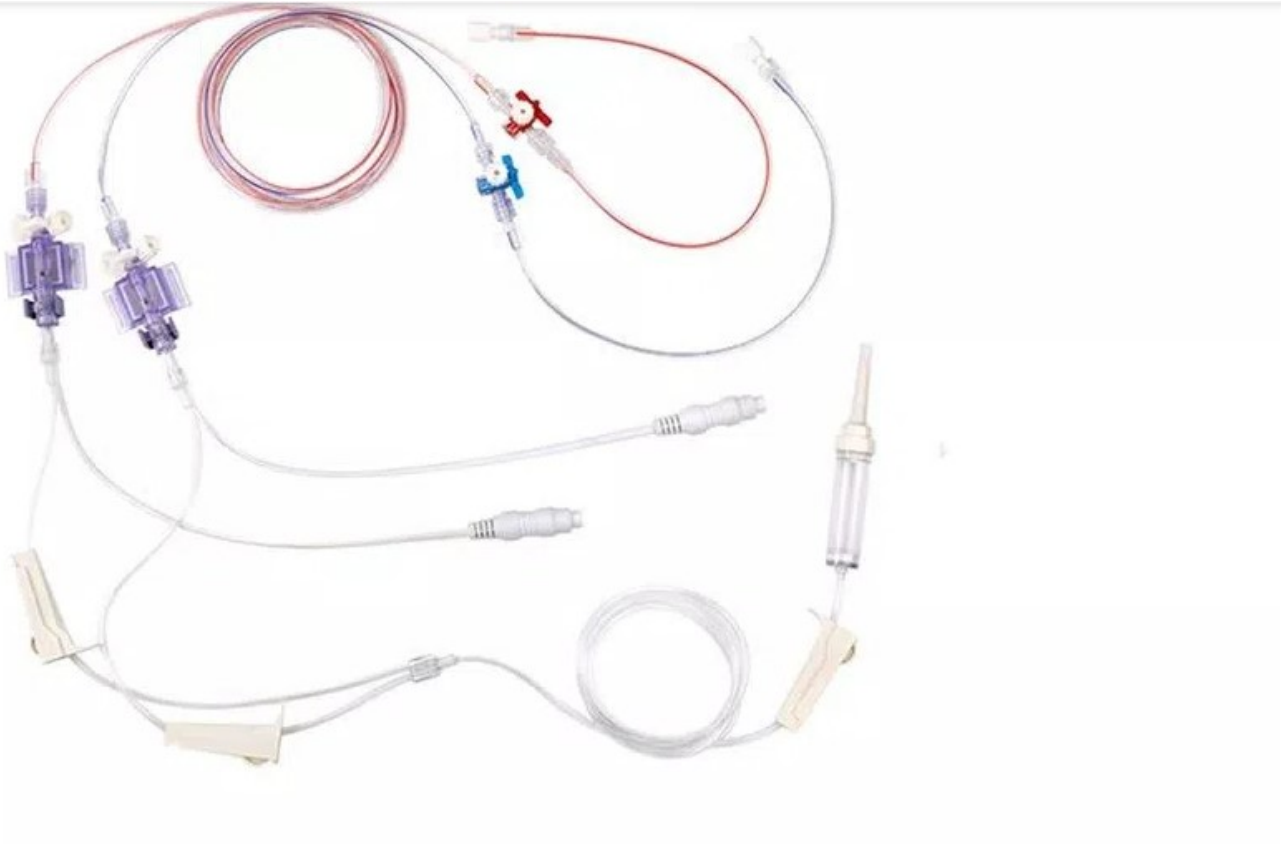

We have 9 different connectors.

Product Name:	Double channel IBP transducer for B braun
Model Number:	JIBPT-02-BL
Material:	Plastic
Certificate:	CE/ISO13485

MEDICAL金成锐医疗 **Shenzhen JCR Medical Technology Limited Company**
Add.: 101, Building 1, Plant B, No.1,Tianfu Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen, Guangdong, China(518132)

EC DECLARATION OF CONFORMITY

The following EC declaration of conformity exemplifies the required content according to Directive 93/42/EEC.

EC DECLARATION OF CONFORMITY

Name and address of the manufacturer: Shenzhen JCR Medical Technology Limited Company
101, Building 1, Plant B, No.1,Tianfu Road, Tianliao Community,
Yutang Street, Guangming District, 518132 Shenzhen, Guangdong,
PEOPLE'S REPUBLIC OF CHINA

We declare under our sole responsibility that

Productname:		Model	GMDN	UMDN
Disposable Transducer	Pressure	JIBPT-01-YP, JIBPT-01-UT, JIBPT-01-BD, JIBPT-01-EDW, JIBPT-01-MD, JIBPT-01-BL, JIBPT-01-PVB, JIBPT-01-USB, JIBPT-01-MR, JIBPT-E-01-YP, JIBPT-E-01-UT, JIBPT-E-01-BD, JIBPT-E-01-EDW, JIBPT-E-01-MD; JIBPT-E-01-BL, JIBPT-E-01-PVB, JIBPT-E-01-USB, JIBPT-E-01-MR.	35927	13114

Guoshuihong

of class: / Class IIb

according to annex IX of directive 93/42/EEC

Shenzhen JCR Medical Technology Limited Company
Add.: 101, Building 1, Plant B, No.1,Tianfu Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen, Guangdong, China(518132)

meets the provisions of the directive 93/42/EEC and its transpositions in national laws which apply to it. The declaration is valid in connection with the "final inspection report" of the device.

Conformity assessment procedure: / Directive 93/42/EEC Annex II, excluding Section 4

Registration No.: **HD 60147227 0001**

Notified Body: **TÜV Rheinland LGA Products GmbH**
Tillystraße 2
90431 Nürnberg
Deutschland
CE 0197

Shenzhen , 2021-11-20.
Place, date /

Guoshuheng Managing Director
Name and function

Product Intended Use:
Disposable Pressure Transducer is used in Medical unit to monitor various pressure such as patient's arterial Pressure venous , central venous pressure,Pulmonary arterial pressure and left coronary pressure. it is a single use product. it can be used with various kinds of invasive blood pressure. This product is only for use of Experienced medical staff and the guidance to directly or in their use.

The principle, function and structure of the product :
After sterilization, one end of the Disposable Pressure Transducer is connected to patient's blood vessel or pressure cavity, the other end is connected to monitor using a disposable cable, through the microcomputer electric wheatstone bridge of the pressure chip, patient's blood pressure or other cavity pressure is converted to electrical signals when the liquid medicine flows through the sensor, and the monitor conducts signal conditioning so as to monitor the pressure in real time.

This product is only for use of Experienced medical staff and the guidance to directly or in their use.

Please refer to the user manual for Disposable Pressure Transducer for details.

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.:	SX 2181190-1
Organization:	Shenzhen JCR Medical Technology Limited Company 101, Building 1, Plant B, No.1, Tianfu Road, Tianliao Community, Yutang Street, Guangming District, Shenzhen 518132 Guangdong P.R. China
Scope:	Design and Development, Manufacture and Distribution of Disposable Pressure Transducers

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.:	10919665-100
Effective date:	2021-12-03
Expiry date:	2024-05-01
Issue date:	2021-12-03

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Dipl.-Ing. W. Hsu
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

DAkkS Deutsche Akkreditierungsstelle D-ZM-14169-01-02

Business Stream Products
Certification Department

TÜVRheinland®
Precisely Right.

TÜV Rheinland LGA Products GmbH • 51105 Köln

Shenzhen JCR Medical Technology
Limited Company
101, Building 1, Plant B, No.1,
Tianfu Road, Tianliao Community,
Yutang Street, Guangming District,
Shenzhen
518132 Guangdong
P.R. China

Contact

Tel. +49 911 655-5225
Mail: medical-products@de.tuv.com

Date December 14, 2021

Application for : **QMS**
Certificate No. : HD 60147227 0001
Requirement : Richtlinie 93/42/EWG
Confirmation letter ID : 2020-05-21_ HD 60147227 0001

Report no. : 10919665-100

Dear Madame or Sir,

Update of information to Certificate no. HD 60147227 0001, issued on 03.12.2021

The change notification received on 10.10.2021 related to the information stipulated on the above mentioned certificate was assessed and information confirmed.
We confirm that the change notification is not considered a significant change in design or intended purpose under Regulation (EU) 2017/745 on medical devices (MDR), Article 120(3).

With this document we would like to confirm the following updated information to the afore mentioned certificate

Revised Manufacturer name

Old Manufacturer name:	Shenzhen JCR Technology Limited Company
New Manufacturer name:	Shenzhen JCR Medical Technology Limited Company

Best regards,

Dipl.-Ing. W. Hsu

Certification body

MS-0045446 rev. 0

TÜV Rheinland
LGA Products GmbH

Am Grauen Stein
51105 Köln
Germany

Headquarter

Tillystraße 2
90431 Nuremberg

Phone. +49 911 655 5225
Fax +49 911 655 5226
service@de.tuv.com
www.tuv.com/safety

EC Certificate

Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

TÜVRheinland®

Registration No.: HD 60147227 0001

Report No.: 17063018 007

Manufacturer:

Shenzhen JCR Technology
Limited Company
101, Building 1, Plant B, No. 1, Tianfu
Road, Tianliao Community, Yutang Street
Guangming District
Shenzhen, Guangdong
518132 Guangdong
P.R. China

Products:

Disposable Pressure Transducers

Replaces Approval, Registration No.: DD 60127887 0001

Expiry Date: 2023-05-01

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2020-05-21

Date: 2020-05-21

Notified Body

Wenxiang Zhang

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle III

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.